

### **DETAILED ACTION**

1. This action is in response to the interview on 4/15/10. As discussed in the interview summary form and for reasons discussed below, the application is in condition for allowance of claims 1-11, 14-19, 22-39, 41-46, 48-55, and 67-72, as amended below.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Issac Hubner on 4/15/10.

#### **The application has been amended as follows:**

Claim 1. (Currently amended) A breath-actuated delivery device, comprising:

a delivery unit which is actuatable to deliver substance on application of a delivery force thereto;

a loading unit which is actuatable to apply the delivery force to the delivery unit to actuate the same;

a mouthpiece through which a subject in use exhales;

an air channel which is in fluid communication with the mouthpiece; and

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an actuating member which is disposed in the air channel, the actuating member comprising a flexible, bi-stable element which is actuatable, on exhalation by the subject into the mouthpiece, between a first, non-actuated state and a second, actuated state in which the actuating member actuates the loading unit to apply the delivery force to the delivery unit to actuate the same,

wherein the loading unit comprises a drive member which is actuatable from a loaded position to actuate the delivery unit, a biasing element for loading the drive member with the delivery force, and a restraining member for normally restraining the drive member in the loaded position and being configured to be released on actuation of the actuating member to the actuated state, such as to cause the biasing element to drive the drive member to actuate the delivery unit; and

wherein the restraining member comprises a tether which is broken on actuation of the actuating member.

Claim 12. (Cancelled)

Claim 13. (Cancelled)

Claim 14. (Currently amended) The delivery device of claim 1 [[13]], wherein the tether comprises at least one filament.

Claim 20. (Cancelled)

Claim 21. (Cancelled)

Claim 22. (Currently amended) The delivery device of claim 1 [[12]], wherein the drive member and the restraining member are formed as a single integral unit.

Claim 23. (Currently amended) The delivery device of claim 1 [[12]], wherein the loading unit further comprises a loading member which is operable to load the biasing element with the delivery force.

Claim 28. (Currently amended) The delivery device of claim 1 [[13]], ~~wherein the loading unit comprises a drive member which is actuatable from a loaded position to actuate the delivery unit, a biasing element for loading the drive member with the delivery force, and a restraining member for normally restraining the drive member in the loaded position and being configured to be released on actuation of the actuating member to the actuated state, such as to cause the biasing element to drive the drive member to actuate the delivery unit; and wherein the loading unit further comprises a releasing element which is operative, on actuation of the actuating member to the actuated state, to release the restraining member.~~

Claim 30. (Currently amended) The delivery device of claim 1, wherein the actuating member is configured to ~~such as~~ substantially to close the air channel such that the actuating member is actuated on generation of a predetermined ~~predeterminable~~ pressure in the mouthpiece.

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Claim 31. (Currently amended) The delivery device of claim 1, wherein the actuating member is configured ~~such as~~ to provide for an air flow through the air channel when in the non- actuated state and close the air channel when in the actuated state.

Claim 32. (Currently amended) The delivery device of claim 1, wherein the actuating member is configured to ~~such as~~ substantially ~~to~~ close the air channel when in the non-actuated state and provide for an air flow through the air channel when in the actuated state.

Claim 33. (Currently amended) The delivery device of claim 1, where the actuating member is configured ~~such as~~ to provide for an air flow at a first rate through the air channel when in the non-actuated state and an air flow at a second rate, higher than the first rate, through the air channel when in the actuated state.

Claim 39. (Currently amended) A delivery device, comprising:

a delivery unit which is actuatable to deliver substance on application of a delivery force thereto; and

a loading unit which is actuatable to apply the delivery force to the delivery unit to actuate the same, the loading unit comprising a drive member which is actuatable from a loaded position to actuate the delivery unit, a biasing element for loading the drive member with the delivery force, and a restraining member, comprising a tether, for normally restraining the drive member in the loaded position and being configured ~~to be~~

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such that the tether is broken on actuation of the loading unit to release the drive member and cause the biasing element to drive the drive member to actuate the delivery unit.

Claim 40. (Cancelled)

Claim 41. (Currently amended) The delivery device of claim 39 [[40]], wherein the tether comprises at least one filament.

Claim 47. (Cancelled)

Claim 48. (Currently amended) The delivery device of claim 39, further comprising:  
an actuating member which is actuatable to break the tether of the restraining member and actuate the loading unit.

Claim 51. (Currently amended) The delivery device of claim 50, wherein the actuating member further comprises a releasing element which is disposed to the bi-stable ~~bistable~~ element thereof and configured to break the tether of the restraining member of the loading unit on actuation of the actuating member to the actuated state.

Claim 52. (Currently amended) The delivery device of claim 50, wherein the loading unit further comprises a releasing element which is operative, on actuation of the actuating member to the actuated state, to break the tether of the restraining member.

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Claims 56-66. (Cancelled)

Claim 67. (New) A method of delivering a substance to a subject, the method comprising the steps of:

- the subject obtaining a device according to any of claims 1-11, 14-19, or 22-33;
- loading the drive member of the device with a predetermined delivery force;
- gripping the mouthpiece of the device in the subject's lips or teeth; and
- exhaling through the mouthpiece.

Claim 68. (New) A method of delivering a substance to the nasal airway of a subject, the method comprising the steps of:

- the subject obtaining a device according to any one of claims 34-38;
- loading the drive member of the device with a predetermined delivery force;
- inserting the nosepiece of the device in one of the subject's nostrils;
- gripping the mouthpiece of the device in the subject's lips or teeth; and
- exhaling through the mouthpiece.

Claim 69. (New) A method of delivering a substance to a subject, the method comprising the steps of:

- the subject obtaining a device according to any of claims 39, 41-46, or 48;
- loading the drive member of the device with a predetermined deliver force; and

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actuating the loading unit of the device so as to cause the release of the drive member and actuation of the delivery unit to deliver the substance to the subject.

Claim 70. (New) A method of delivering a substance to a subject, the method comprising the steps of:

- the subject obtaining a device according to any of claims 49-53;
- loading the drive member of the device with a predetermined delivery force;
- gripping the mouthpiece of the device in the subject's lips or teeth; and
- exhaling through the mouthpiece so as to actuate the actuating member to cause the actuation of the loading unit.

Claim 71. (New) A method of delivering a substance into the nasal airway of a subject, the method comprising the steps of:

- the subject obtaining a device according to claim 54;
- loading the drive member of the device with a predetermined delivery force;
- fitting the nosepiece of the device to a nostril of the subject; and
- actuating the loading unit of the device so as to cause the release of the drive member and actuation of the delivery unit to deliver the substance through the nosepiece and into the nasal airway of the subject.

Claim 72. (New) A method of delivering a substance into the nasal airway of a subject, the method comprising the steps of:

the subject obtaining a device according to claim 55;  
loading the drive member of the device with a predetermined delivery force;  
gripping the mouthpiece of the device in the subject's lips or teeth;  
fitting the nosepiece of the device to a nostril of the subject; and  
exhaling through the mouthpiece so as to actuate the actuating member to cause the actuation of the loading unit.

### **REASONS FOR ALLOWANCE**

3. The following is an examiner's statement of reasons for allowance: when read in light of the limitations of the claimed breath-actuated delivery device, the prior art of record by itself or in combination does not disclose the specific structure and relationship as recited in claims 1 and 39 such that the loading unit includes a drive member actuatable from a loaded position, a biasing element for loading the drive member with the delivery force, a restraining member which comprises a tether for restraining the drive member in the loaded position and configured to be released on actuation (via user exhalation; claim 1) such as to cause the biasing element to drive the drive member to actuate the delivery unit wherein the tether is broken on actuation of the actuating member.

The closest prior art references are: Djupesland (2005/0028812), Fugelsang et al. (2002/0157664), King (5,738,087), and Christrup et al. (2004/0079362) which all relate to actuatable (via breath or other trigger mechanism) delivery devices.



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The prior art of record does not disclose the structural limitations related to the loading unit including a drive member which is loaded with delivery force by the biasing element and includes a restraining member comprising a tether which is broken on actuation of the actuating member and releases the drive member to actuate the delivery unit, as discussed above.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/  
Examiner, Art Unit 3771

/Steven O. Douglas/  
Primary Examiner, Art Unit 3771